Nurse-led follow-up care for head and neck cancer patients: a quasi-experimental prospective trial

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Abstract

Purpose The aim of this study was to compare conventional medical follow-up with follow-up containing additional nursing consultations regarding the psychosocial adjustment and health related quality of life (HRQOL) of head and neck cancer patients.

Methods Using a quasi-experimental design, patients were enrolled consecutively into two groups. Experimental care covered six 30-minute bimonthly nursing follow-up consultations during the first year posttreatment. Data were collected at posttreatment months 1 (baseline), 6 and 12 for both groups.

Results The intervention group was significantly worse at baseline, based on two of the seven adjustment scales and on the majority of HRQOL scales. However, their outcome at 6 and 12 months was consistent with that of the group which received conventional follow-up. Thus, the intervention group had a larger improvement in scores, and this was significant for one of the seven adjustment scales and 19 of the HRQOL scales at 6 and 12 months, respectively. Most of the differences in HRQOL scales were clinically relevant at 6 months.

Conclusion These results suggest that nurse-led consultations for patients with head and neck cancer have a positive effect, primarily with respect to HRQOL. Nurse-led follow-up leads to a similar psychosocial adjustment as conventional follow-up, even among patients who showed worse performance at the start of follow-up. Thus, nurse-led follow-up may be a cost-effective way to improve follow-up care for this patient group.

Trial registration Clinicaltrials.gov (NCT01167179)

Introduction

It is generally accepted that regular posttreatment surveillance is important for the general well-being of cancer patients, for the management of (late) complications, and for detecting recurrence of cancer in an asymptomatic stage. [1] It is also recognized that long-term routine follow-up in head and neck cancer (HNC) patients does not lead to improved survival and is inefficient at detecting recurrence. [2-4] For HNC patients, a rigid one-size-fits-all approach of follow-up is questionable, and there is currently an ongoing professional debate to determine the optimum duration and content of follow-up care. [4] However, other goals of follow-up care, (e.g., management of (late) complications, evaluation of treatment and psychosocial care) remain crucial and are being increasingly recognized as an important standard of care for cancer management. [1]

Specialized nurses are frequently considered as the appropriate professionals for assuming a role in cancer follow-up. [5-7] With regard to cancer populations such as breast, lung, prostate, colorectal and oesophageal cancer patients, nurse-led care has been found to be acceptable, appropriate and effective, and does not adversely affect patient quality of life compared with standard follow-up care by clinicians. [8-12] In a study of nurse-led follow-up for HNC patients undergoing radiotherapy, positive effects were found with respect to attendance at follow-up visits and no differences regarding health related quality of life (HRQOL) scores compared with physician appointments. [6]

In recent years, the Head and Neck Oncology Centre at our institute tested an integrated care program for HNC patients. The results suggested improvement, particularly with respect to information and psychosocial support. [13] Upon confirming the results by interviews with 21 HNC patients regarding the management of their discharge advice and posttreatment care, it was decided to start the current study. [14]

In this trial, we compared predominantly medically oriented follow-up (i.e., conventional care) with follow-up that was expanded using structured nursing consultations (i.e., experimental care), focusing on supportive care and simple medical control checks. We hypothesized that the experimental care would result in improved patient outcomes on psychosocial adjustment and HRQOL relative to conventional care.

Materials and methods

Study design and setting

This quasi-experimental prospective single-center study was conducted at the Radboud University Center for Oncology in Nijmegen, the Netherlands. The study was a full-scale pilot in accordance with the guidelines of the Medical Research Council (MRC) Framework for the Evaluation of Complex Interventions. [15, 16] A comparison group (n=80) and (after providing a training for nurses) an intervention group (n=80) were recruited consecutively. Ethical approval was obtained from the regional Medical Ethical Committee (CMO-nr. 2007/113), and the study was conducted in accordance with the Declaration of Helsinki. [17, 18]

Participants

The eligibility criteria for the study were as follows: informed of a HNC diagnosis (but no other cancer); to be treated with curative intent; to be able to speak, write and understand Dutch; and be cognitively able to provide informed consent. Exclusion criteria included overt psychopathology, alcohol addiction, and/or a life expectancy of less than 6 months. HNC patients who attended a weekly screening session were identified and approached by oncology nurses. For this purpose, the nurses used a written scenario. All participants provided a written informed consent. Patients were recruited to the comparison and intervention groups from November 2007 to July 2008 and from January 2009 to February 2010, respectively. A total of 170 eligible patients were asked to participate. Ten patients refused: six were not willing to participate, two preferred physician follow-up only, and two declined for other reasons.

The nurse participants were registered nurses currently working as legal registered oncology nurses. All of the nurses were female, (mean age 43 years) with a mean experience in the HNO field of 11 years (range 6-20 years). Nurses were eligible if they had indicated a willingness to receive training and supervision and to have their performance evaluated on a regular basis.

One nurse unexpectedly withdrew from the study. A new nurse was recruited and individually trained and instructed by the researcher. Subsequently, this nurse participated in the supervision, coaching and video recording as planned. To compensate for this delay, the recruitment period for the intervention group was extended by 2 months.

Procedure

Conventional care

The participants in the comparison group received conventional care that consisted of a 5-year routine control schedule with six bimonthly 10-minute visits to a head and neck surgeon in the first year posttreatment in accordance with national guidelines. [19] Nursing follow-up care consisted of ad hoc problem-based contacts except for patients who underwent a laryngectomy, who received standard nursing consultations during the first 6 months posttreatment in parallel with the medical control visits. Patients who were treated with surgery alone all had one standard wound control visit with a nurse; patients who were treated with radiotherapy had one to six ad hoc nursing contacts during the first 6 months posttreatment. For the duration of the study, there were no changes in conventional care.

Experimental care

The intervention consisted of six 30-minute nursing follow-up consultations in the first year posttreatment. A standardized protocol was used for this purpose. Nursing consultations were conducted in parallel with and preceding the medical routine control visits and included a needs assessment based upon the biopsychosocial model. [20] The aim of consultation was to give advice and support to patients (and their partners) addressing the physical and psychosocial consequences of treatment. To increase patient focus and active participation during consultations, patients completed a 13-item checklist prior to each consultation. [14, 21-23] Every 3 months, patients were screened for psychosocial problem areas using a specific questionnaire. [24]

During the consultations, the nurses also performed simple medical checks including inspection of the tracheal stoma, cannula and speech valve (if applicable), and oral cavity, and palpation of the neck and lymph nodes.

Training of nurses

Before recruiting patients to the intervention group, nurses participated in two 3-hour training sessions for the following items: 1) information regarding the biopsychosocial model and 2) performing a consultation using exploratory communication skills. Training sessions were developed and delivered in collaboration with a clinical psychologist (author J.P.). Also, two head and neck surgeons delivered a 2-hour training session regarding how to perform simple medical checks. During the intervention period, nursing supervision meetings were planned every 2 months led by a clinical psychologist (J.P.). The aims were to share experiences from consultations, provide collegiate support, and address issues that obstructed execution of the intervention. Individual coaching of nurses was offered by the researcher by attending several consultations followed by reflective conversations afterwards.

Outcome measures

The primary outcomes were psychosocial adjustment and HRQOL. Psychosocial adjustment can be viewed as "the adaptive psychosocial response of an individual to a significant life change" [25] and was assessed using the Psychosocial Adjustment to Illness Scale – Self Report (PAIS-SR), a 46-item self-report measure that assesses changes in seven domains. A mean PAIS-SR T-score of 50 is the average score for each domain, meaning that patients with this score adjusted neither better nor worse than a mixed cancer reference group, whereas a score lower than 50 indicates better adjustment. The PAIS-SR is well validated and has been used in previous studies of HNC patients. [26-28] Here, we used the validated Dutch translation. [29]

HRQOL can be defined as; "a state of physical, mental and social well-being and not merely absence of disease or infirmity". [30] HRQOL was measured with the European Organisation of Research and Treatment of Cancer Quality of Life Questionnaire with additional Head & Neck Module (EORTC QLQ-C30 and QLQ-H&N35). [31, 32] These are cancer-specific patient-based self-report questionnaires, and the psychometric properties of both have been tested thoroughly in several studies. [33, 34] The core questionnaire was composed of five functioning scales, a global health status/QOL scale, and nine symptom scales. The additional H&N35 module contained 18 disease-specific symptom scales. All EORTC scores were transformed to a 0-100 scale in accordance with the procedures in the scoring manual. [32] A high score for the functional scales and for the global health status/QOL scale represents a high level of functioning, whereas a high score on a symptom scale represents a high level of symptoms.

Data collection

Data were collected from November 2007 to March 2011. Patient demographic and disease-related characteristics were retrieved from patient records. Questionnaires were delivered 1, 6 and 12 months after treatment. The baseline moment of the 1-month posttreatment questionnaire was set to a week before the first nursing consultation. To increase patient compliance in returning questionnaires several steps were taken, including postage-paid return envelopes, a postal reminder after one month, and, if necessary, a repeat postal reminder 1 month later together with a new set of questionnaires.

Statistical analysis

SPSS 18.0 was used to analyze the descriptive data. Baseline differences between groups with respect to sociodemographic and disease characteristics were tested using χ^2 test. Data were analyzed on an intention-to-treat basis. To account for the similarity of each measurement within patients, a linear mixed model for repeated measurements was applied to analyze the effect of nurse-led follow-up consultations on the primary outcome variables. These models also account for missing data (provided that the missing data were missing at random). The SAS software package (version 8.2) was used to fit the models. Intervention and time (as well as their interaction) and the adjustment factors tumor location, size of the tumor (stage I, II vs. stage III, IV), treatment modality, living without a partner, and education (high vs. other) were included in the model as fixed effects. Differences between groups at baseline, 6, and 12 months, and differences in change from baseline to 6 and 12 months were estimated from this model. An unstructured covariance matrix was fitted.

To facilitate the interpretation of scores of differences in changes from baseline, the frequency of clinically relevant changes was analyzed. A clinically relevant change in PAIS-SR was defined as a change of 1 standard deviation (10 units) in mean T-score compared to the preceding measurement. [26] For the EORTC, a clinically relevant change was defined as change of 10 points in mean scores. [35]

No formal power calculation was performed, as this study was an exploratory trial. The sample size was determined by taking into consideration the number of patients lost due to recurrence of cancer and/or death.

Treatment fidelity

Several measures were taken to strengthen treatment fidelity in this study. [36] All of the nurses had similar levels of education, which is relevant when group training is provided. During training, standardized materials and role playing were used. To minimize the drift of skills after training, supervision meetings and individual coaching sessions were offered for the duration of the intervention period. To help the nurses and to improve delivery of the intervention as intended, we used a standardized consultation protocol. Additionally, video recordings of consultations were used to verify the actual professional performance (results will be reported elsewhere), and the researcher maintained contact with nurses several times per week to monitor intervention delivery, and to serve as a consultant.

Results

Demographic and disease characteristics are shown in Table 1. Both, educational level and treatment modality differed significantly between groups. No explanation other than coincidence was found to account for the difference in educational level. During the recruitment period of the intervention group, there was an increase in chemoradiation treatment for patients with stage III or IV malignancies. Consequently, more patients in the intervention group received this treatment, and this accounts for the difference in treatment modality between groups.

Response rate

At 12 months, 124 patients (78%) had returned their mailed questionnaires. The reasons for nonresponse were distributed as follows for the intervention and comparison groups, respectively: recurrence of disease, 4/4; death, 10/4; withdrawal from study, 2/1; other reasons, 5/6 patients. The number of non-responses was distributed evenly between the groups at 6 and at 12 months, with the exception of "death" (at 6 months, eight and two patients had died in the intervention and comparison groups, respectively).

Psychosocial Adjustment

The baseline mean scores for the PAIS-SR (Table 2) were significantly worse in the intervention group for the domains of health care orientation, social environment and total adjustment (p =<0.05). At 6 months, no significant differences were observed between groups; at 12 months, health care orientation differed significantly between groups (p=<0.02), although the difference never exceeded 1 standard deviation. Table 4 shows the results from the mixed model analysis. No significant difference between groups was detected in the change from baseline in PAIS-SR scores at 6 and 12 months, with the exception of the domain of social environment, in which the intervention group had significant worse scores at baseline (p=<0.05) but a 7.8-point (95%-CI=2.3, 13.2) and 6.7-point (95%-CI=1.3, 12.2) larger improvement than the comparison group at 6 and 12 months, respectively.

Analyses of clinically relevant changes are presented in Table 5. Nearly equal numbers of patients in both groups had improved by at least 1 standard deviation at 6 and 12 months. With respect to deterioration, however, at 6 months, more patients had deteriorated in the intervention group than in the comparison group. The largest difference was in the domain of social environment, with twice as many deteriorated patients in the intervention group as in the comparison group (27 vs. 13 patients, respectively). At 12 months, the number of deteriorated patients was approximately equal between groups.

Health Related Quality of Life

For most of the EORTC scales, baseline mean scores were significantly worse (p=<0.05) for the intervention group (Table 2). At 6 and 12 months, the mean scores were not significantly different between groups. At 6 and 12 months, differences in scores with respect to changes from baseline were significantly larger for the intervention group for many of the EORTC scales (Table 4). This was the case for 3 of the 5 functional scales, for global health status/QOL, for 6 of the 9 generic symptom scales, and 9 of the 18 specific head and neck scales at each time point. The most robust clinically relevant changes (i.e., a change of 10 points or more on a given scale) occurred at 6 months (see Table 5). For many items, more patients improved in the intervention group than in the comparison group. A difference of 10 patients or more (in favor of the intervention group) was observed for 3 of the 5 functional scales, for global health status/QOL, for 3 of the 9 generic symptom scales, and for 11 of the 18 specific head and neck scales. The largest difference between groups was seen with respect to fatigue at 6 months and for pain and social eating at 12 months, both differences favoring the intervention group.

Aspects of treatment fidelity

To determine to which extent the intervention was executed as planned, several aspects were evaluated. Patient participation in nursing follow-up consultations was deemed to be good; 480 consultations were planned, and 389 (81%) were realized. In addition, 70% (n=56) of the patients attended all consultation sessions. The reasons

for failing to attend a consultation included: recurrence of disease and/or death (*n*=14), planning errors (*n*=5), withdrawal from study (*n*=2), and other causes (*n*=3). In 49% (189) of consultations nurses independently performed medical checks, 154 of which were verified by a physician (Table 3). In 37% (145) of the consultations, the nurses did not execute medical checks, but rather asked a physician for this task. This latter group of consultations was for laryngeal patients, as the required laryngoscopy had to be performed by a physician: thus, to minimize patient burden, nurses asked the physician to perform the other medical control checks as well. In 14% (55) of the nursing consultations, it was unclear whether (and how) medical checks were performed, as registration information was missing. The nurses themselves reported that the majority of consultations could be performed adequately within 30 minutes, and they reported an increase in work satisfaction, as they were now (in their words) "finally doing what I'm trained for".

Discussion

Cancer follow-up is shifting slowly from the detection of recurrence towards the management of several aspects of cancer survivorship. Specialized oncology nurses are increasingly embedded in a multidisciplinary cancer care team to provide symptom management and supportive follow-up care. Several reviews have suggested that this care has the potential to add quality to cancer care and decrease costs; however, there is currently a paucity of sound economic evaluation research. [37, 38] Substituting nurses for doctors is a potential next step in cancer care, but additional research is needed before nurse-led follow-up care can be considered equivalent to physician-led follow-up care in terms of survival, recurrence, and cost-effectiveness. Patient perspective with respect to follow-up care seems to be shifting as well. In a recent survey in the UK, when 263 HNC patients were asked, "who they would like to contact in a system based on patient-reporting problems and requesting appointments," 45% (118 patients) stated a preference for a clinical nurse specialist. [39]

The results of our study show that nurse-led follow-up had positive effects on HRQOL, although effects were small and were not statistically significant. In the intervention group, in patients who were initially worse at baseline, psychosocial adjustment and HRQOL scores at 6 and 12 months reached same levels as in patients in the comparison group, which had received conventional care. Therefore, the differences in the changes in scores from baseline between groups were significantly larger for the intervention group, and this effect was primarily in the HRQOL scores. More clinically relevant changes were more observed in the intervention group at 6 months for many of the disease-specific and generic HRQOL scores.

Patients in both groups experienced few significant problems with psychosocial adjustment (PAIS-SR). In a study by Vickery et al., a total adjustment score at 6-18 months posttreatment of 47-51 was reported. [28] In both our study groups, scores were lower, suggesting improved overall adjustment. Greer et al. [40] applied the PAIS-SR in a prospective design and tested a psychological therapy intervention in 174 patients, 9 of whom were HNC patients. In this randomized trial, no significant differences between groups persisted at the 4-month follow-up, with the exception of the domain of psychological distress. The mean total adjustment score in the experimental group was 50. At baseline (1 month post treatment), our intervention group reported minor disturbances in adjustment; therefore, possibilities for improvement were perhaps somewhat limited. The domain of health care orientation showed a small but significant difference in mean scores at 12 months in favor of the comparison group. This domain concerns the patient's perspective regarding health and health care. No explanation for this difference can be given except perhaps increased "health care awareness" among patients in the intervention group as a result of nurse-patient conversations causing a slightly more critical score in this domain. Because we did not measure pretreatment scores, it is unclear whether (and to what extent) any psychosocial adjustment had occurred during the course of treatment. It would be interesting, however, to determine how adjustment scores in disease-free HNC patients will develop over the coming years. This is particular important for patients with a permanent impairment and/or long-term symptom burden.

The EORTC questionnaire combined with the H&N35-module is a sensitive instrument for detecting differences in this patient population. The results of the HRQOL scores were more disparate than those of the PAIS-SR. Although there were no differences in mean scores between groups 6 or 12 months, clinically relevant changes were more prevalent in the intervention group, thereby supporting the results of the mixed model analyses. In agreement with other HNC studies, the largest improvement in HRQOL scores in both groups occurred in the first six months posttreatment. [41, 42]

In considering these findings, it is important to acknowledge the study's limitations. A key issue is the study design, which lacked randomization; thus, possible confounding factors may have influenced the results. The quasi-experimental design also limited the possibility of assessing causality. Due to practical and organizational limitations, conducting a randomized controlled trial was not feasible. Specifically, contamination was a potential problem, due to a small nursing staff (three nurses). Thus, a quasi-experiment (pre-test, post-test) with a historical control group was the best alternative.

In conclusion, oncology nurses can contribute considerably to further development and advancement of follow-up care for HNC patients. Although our single institution setting and some methodological disadvantages limit the findings, our results imply potential value and suggest improved outcomes for HNC patients. The nurse-led model that we used can be readily modified for use in other (cancer) patient populations. Future research regarding nurse-led follow-up care for HNC patients should focus on improvement of the intervention program, and on continued evaluation of patient's outcomes, including HRQOL. A possible multi center implementation study of this nurse-led program combined with a thorough economic evaluation would provide valuable additional information for cancer follow-up care.

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Disclosures: None.

Table 1 Demographic and disease characteristics per group

	Intervention group (*n*=80)	Comparison group (*n*=80)
Gender		
Male	54 (67.5)	60 (75)
Age, years		
Mean [range]	58.4 [22-86]	59.2 [30-83]
Marital status		
Living with partner	56 (70.9)	58 (73.4)
Occupational status		
Employed	52 (67.5)	43 (55.8)
Educational level[a]		
High	29 (36.3)	14 (18.2)
Medium	19 (23.8)	22 (28.6)
Low	32 (40.0)	41 (53.2)
Caucasian race	79	80
Cancer site		
Larynx	14 (17.5)	23 (28.8)
Hypopharynx	7 (8.8)	1 (1.3)
Oropharynx	15 (18.8)	10 (12.5)
Oral cavity	32 (40.0)	34 (42.5)
Other	10 (12.5)	10 (12.5)
Stage (UICC – 2011)		
I	24 (30.0)	30 (37.5)
II	19 (23.8)	22 (27.5)
III	10 (12.5)	7 (8.8)
IV	24 (30.0)	12 (15.0)
No stage	2 (2.5)	0
Treatment modality[a]		
Surgery only	34 (42.5)	50 (62.5)
Surgery + Radiotherapy	11 (28.8)	9 (22.5)
Radiotherapy alone	23 (13.8)	18 (11.3)
Chemoradiation	12 (15.0)	1 (1.3)
Laser surgery	0	2 (2.5)

Figures in parentheses are percentages

[a] Significant difference between the groups (χ^2 - test)

Table 2 Mean (SD) scores of PAIS-SR and EORTC QLQ-C30 / EORTC QLQ-H&N35 at baseline, 6 and 12 months (*n*=160)

	Baseline (SD)				**6 months (SD)**				**12 months (SD)**			
PAIS-SR [a]	**intervention group**		**comparison group**		**intervention group**		**comparison group**		**intervention group**		**comparison group**	
Health care orientation	54	(10) *	50	(8)	51	(8)	49	(9)	52	(9) *	48	(8)
Vocational environment	62	(7)	59	(7)	57	(7)	56	(7)	54	(7)	54	(7)
Domestic environment	46	(9)	44	(9)	43	(9)	42	(9)	42	(9)	41	(9)
Sexual relations	49	(9)	47	(9)	46	(8)	47	(9)	46	(8)	47	(9)
Extended family relations	49	(8)	50	(8)	49	(7)	52	(8)	49	(7)	49	(7)
Social environment	51	(15) *	45	(15)	43	(15)	43	(13)	42	(14)	42	(13)
Psychological distress	49	(10)	46	(10)	45	(10)	45	(10)	45	(11)	43	(10)
Total adjustment	50	(11) *	46	(12)	44	(12)	44	(13)	43	(13)	42	(12)
EORTC QLQ-C30												
Functional Scales [b]												
Physical functioning	71	(23) *	86	(17)	83	(17)	86	(16)	86	(17)	87	(16)
Role functioning	54	(32) *	75	(27)	79	(26)	81	(24)	81	(27)	85	(25)
Emotional functioning	80	(24)	83	(18)	84	(19)	85	(19)	82	(23)	85	(18)
Cognitive functioning	81	(23)	87	(19)	88	(17)	87	(17)	87	(20)	86	(21)
Social functioning	76	(25) *	88	(22)	91	(15)	90	(16)	90	(19)	91	(21)
Global health status/QOL	64	(23) *	76	(17)	77	(16)	80	(18)	81	(18)	80	(17)
Symptom scales [c]												
Fatigue	46	(29) *	29	(23)	24	(21)	25	(23)	19	(25)	22	(24)
Nausea/vomiting	15	(29) *	7	(15)	3	(13)	4	(13)	3	(13)	4	(10)
Pain	35	(29) *	18	(22)	15	(22)	14	(23)	12	(22)	15	(22)
Dyspnea	19	(26) *	9	(18)	10	(20)	14	(23)	12	(21)	12	(19)
Insomnia	29	(29)	23	(29)	20	(28)	18	(25)	19	(30)	18	(25)
Appetite loss	29	(35) *	12	(24)	13	(23)	9	(19)	7	(17)	8	(21)
Constipation	21	(30) *	10	(19)	8	(21)	6	(14)	7	(18)	6	(15)
Diarrhea	10	(23)	7	(17)	5	(15)	6	(16)	4	(11)	8	(18)
Financial difficulties	10	(25)	8	(15)	7	(17)	8	(20)	8	(22)	7	(15)
EORTC QLQ-H&N35												
Symptom scales [c]												
Pain	38	(24) *	25	(22)	15	(16)	15	(14)	14	(17)	14	(18)
Swallowing	37	(30) *	20	(21)	4	(18)	11	(16)	9	(19)	10	(15)
Senses	29	(30) *	16	(20)	17	(24)	14	(21)	18	(26)	15	(23)
Speech	29	(27) *	17	(20)	12	(21)	8	(15)	11	(19)	10	(19)
Social eating	34	(27) *	16	(21)	15	(18)	9	(19)	10	(19)	9	(17)
Social contact	12	(18) *	6	(11)	6	(10)	4	(9)	5	(12)	3	(8)
Less sexuality	31	(35)	20	(29)	19	(26)	20	(29)	19	(27)	15	(23)
Teeth problems	15	(28)	23	(31)	15	(28)	17	(27)	11	(24)	12	(24)
Opening mouth	43	(35) *	24	(31)	17	(29)	14	(23)	11	(21)	10	(21)
Dry mouth	47	(36)	44	(30)	41	(33)	38	(35)	38	(34)	33	(33)
Sticky saliva	47	(38) *	33	(34)	34	(32)	23	(32)	25	(32)	22	(29)
Coughing	33	(33) *	20	(26)	16	(23)	20	(30)	20	(26)	15	(25)
Feeling ill	28	(33)	18	(26)	6	(17)	12	(24)	7	(22)	9	(18)
Use of pain killers	63	(49) *	43	(50)	29	(46)	24	(43)	22	(42)	22	(42)
Use of nutritional supplements	44	(50) *	22	(42)	22	(42)	13	(34)	9	(28)	8	(27)
Use of feeding tube	15	(36)	6	(24)	3	(18)	0	(0)	3	(18)	2	(12)
Weight loss	56	(50) *	26	(44)	16	(37)	17	(38)	15	(36)	13	(33)
Weight gain	13	(34) *	29	(46)	26	(44)	35	(48)	27	(45)	34	(48)

‡ $p<0.05$ (significant at this level, *t*-test for independent samples)

[a] PAIS-SR: Compared to a mixed cancer reference group, scores > or < 50 indicate worse or better adjustment, respectively

[b] EORTC: Higher score, better functioning (range 0-100)

[c] EORTC: Higher score, more symptoms (range 0-100)

Table 3 Medical control checks by nurses during nursing consultations (389 consultations)

	laryngeal patients	all other HNC patients	no. (%)
Independent	1	34	35 (9)
Independent + checked by physician	5	149	154 (40)
Not executed, and asked physician	145	0	145 (37)
Missing (performance not registered)	42	13	55 (14)
Total	193	196	389

Figures are number of consultations. Figures between parentheses are percentages.

Table 4 Differences in change from baseline (i.e., 1 month after medical treatment) at 6 and at 12 months

	Baseline score (p value)[a]	**6 months** Change from baseline (95%CI)[a]		p-value*	**12 months** Change from baseline (95%CI) [a]		p-value*
PAIS-SR							
Health care orientation	2.6 (0.12)	-0.6	(-3.6,2.5)	0.71	0.0	(-3.1,3.2)	0.98
Vocational environment	2.7 (0.03)	-0.7	(-3.2,1.9)	0.59	-2.4	(-5.0,0.2)	0.07
Domestic environment	2.8 (0.09)	-1.8	(-4.7,1.2)	0.24	-2.4	(-5.4,0.6)	0.12
Sexual relations	0.7 (0.65)	-2.0	(-4.8,0.7)	0.15	-2.4	(-5.4,0.5)	0.11
Extended family relations	-1.0 (0.39)	-0.6	(-3.5,2.1)	0.64	0.3	(-2.2,2.9)	0.80
Social environment	5.1 (0.04)	-7.8	(-13.2,-2.3)	0.01	-6.7	(-12.2,-1.3)	0.02
Psychological distress	3.6 (0.07)	-1.8	(-5.1,1.5)	0.29	-1.2	(-4.5,2.2)	0.49
Total adjustment	3.3 (0.13)	-3.6	(-7.5,0.4)	0.07	-3.5	(-7.5,0.6)	0.09
EORTC QLQ-C30							
Functional Scales							
Physical functioning	-13.1 (0.00)	11.3	(4.3,18.4)	0.00	12.7	(5.8,19.7)	0.00
Role functioning	-17.8 (0.00)	21.1	(9.8,32.5)	0.00	17.3	(4.1,30.4)	0.01
Emotional functioning	-5.6 (0.18)	1.0	(-5.8,7.7)	0.77	1.0	(-6.0,8.0)	0.78
Cognitive functioning	-5.2 (0.21)	4.4	(-2.7,11.4)	0.22	5.9	(-1.3,13.1)	0.11
Social functioning	-12.4 (0.01)	12.9	(4.9,21.0)	0.00	11.5	(1.9,21.0)	0.02
Global health status/QOL	-10.4 (0.00)	8.7	(1.1,16.3)	0.02	12.1	(4.6,19.7)	0.00
Symptom scales							
Fatigue	15.5 (0.00)	-17.6	(-26.8,-8.3)	0.00	-19.2	(-29.1,-9.3)	0.00
Nausea/vomiting	9.3 (0.03)	-8.9	(-16.0,-1.9)	0.01	-10.3	(-17.9,-2.7)	0.01
Pain	16.7 (0.00)	-14.4	(-24.1,-4.7)	0.00	-17.9	(-27.7,-8.1)	0.00
Dyspnea	9.7 (0.02)	-15.2	(-24,-6.4)	0.00	-10.8	(-19.1,-2.5)	0.01
Insomnia	5.2 (0.37)	-3.2	(-14.0,7.5)	0.55	-3.3	(-14.1,7.5)	0.55
Appetite loss	12.8 (0.02)	-10.4	(-20.6,-0.2)	0.04	-17.0	(-27.3,-6.7)	0.00
Constipation	14.3 (0.00)	-9.7	(-18.8,-0.7)	0.04	-12.2	(-21.2,-3.3)	0.01
Diarrhea	2.5 (0.52)	-2.5	(-9.9,4.8)	0.50	-6.8	(-15.8,2.1)	0.13
Financial difficulties	3.0 (0.43)	-2.9	(-10.3,4.4)	0.43	-1.5	(-0.9,6.3)	0.71
EORTC QLQ-H&N35							
Symptom scales							
Pain	12.2 (0.01)	-11.2	(-19.5,-3.0)	0.01	-13.1	(-22.5,-3.7)	0.01
Swallowing	17.7 (0.00)	-12.2	(-21.5,-2.8)	0.01	-18.3	(-27.1,-9.4)	0.00
Senses	10.2 (0.02)	-9.6	(-17.1,-2.1)	0.01	-11.5	(-20.1,2.8)	0.01
Speech	13.3 (0.00)	-4.6	(-12.3,3.1)	0.24	-10.1	(-18.6,-1.7)	0.02
Social eating	17.1 (0.00)	-10.9	(-19.0,-2.9)	0.01	-17.2	(-26.3,-8.2)	0.00
Social contact	7.0 (0.02)	-4.5	(-9.5,0.6)	0.09	-5.1	(-10.2,-0.1)	0.05
Less sexuality	10.0 (0.09)	-11.5	(-21.8,-1.3)	0.03	-8.8	(-20.7,3.2)	0.15
Teeth problems	-7.5 (0.19)	10.3	(-3.5,19.3)	0.17	10.2	(-0.9,21.4)	0.07
Opening mouth	15.6 (0.01)	-15.0	(-27.9,-2.2)	0.02	-18.4	(-30.6,-6.2)	0.00
Dry mouth	-2.0 (0.75)	0.4	(-8.8,9.5)	0.94	3.5	(-7.7,14.7)	0.53
Sticky saliva	8.0 (0.21)	-4.0	(-16.1,8.0)	0.51	-8.7	(-20.9,3.5)	0.16
Coughing	13.6 (0.01)	-13.8	(-24.7,-2.9)	0.01	-6.1	(-16.8,4.6)	0.26
Feeling ill	10.7 (0.05)	-13.8	(-24.6,-2.9)	0.01	-10.5	(-20.6,-0.4)	0.04
Use of pain killers	20.7 (0.03)	-16.2	(-38.1,5.7)	0.15	-19.4	(-41.9,3.2)	0.09
Use of nutritional supplements	19.8 (0.02)	-12.8	(-30.3,4.6)	0.15	-21.0	(-38.5,-3.5)	0.02
Use of feeding tube	9.3 (0.12)	-5.4	(-18.0,7.2)	0.40	-6.8	(-19.2,5.5)	0.27
Weight loss	25.3 (0.01)	-27.3	(-47.0,-7.6)	0.01	-25.4	(-47.4,-3.5)	0.02
Weight gain	5.4 (0.49)	6.6	(-13.1,26.3)	0.51	10.3	(-10.6,31.1)	0.33

* $p<0.05$ (significant at this level)

[a] Negative values for differences favor the intervention group

Table 5 Clinically relevant changes (better or worse) in both groups at 6 and at 12 months

	6 months				**12 months**			
	improved		deteriorated		improved		deteriorated	
	i-group *n* (%)	c-group *n* (%)	i-group *n* (%)	c-group *n* (%)	i-group *n* (%)	c-group *n* (%)	i-group *n* (%)	c-group *n* (%)
PAIS-SR [a]								
Health Care Orientation	6 (9)	7 (10)	11 (17)	6 (8)	3 (5)	8 (12)	4 (7)	11 (17)
Vocational environment	4 (6)	1 (1)	17 (26)	11 (15)	1 (2)	4 (6)	9 (15)	7 (11)
Domestic Environment	6 (9)	8 (11)	10 (16)	6 (8)	3 (5)	7 (11)	6 (10)	9 (14)
Sexual Relations	5 (8)	2 (3)	11 (18)	2 (3)	4 (7)	2 (3)	7 (12)	5 (8)
Extended Family Relations	9 (15)	11 (16)	8 (13)	7 (11)	4 (7)	4 (6)	6 (11)	13 (20)
Social Environment	9 (14)	14 (20)	**27** (41)	**13** (15)	8 (13)	7 (11)	8 (14)	12 (18)
Psychological Distress	6 (9)	8 (11)	16 (25)	11 (16)	6 (10)	8 (12)	8 (14)	9 (14)
Total Adjustment	7 (11)	11 (15)	23 (35)	17 (24)	5 (8)	8 (12)	9 (15)	15 (23)
EORTC QLQ-C30 [b]								
Functional Scales								
Physical functioning	**30** (48)	**13** (19)	10 (16)	8 (11)	15 (25)	7 (11)	5 (9)	4 (6)
Role functioning	**39** (63)	**28** (41)	11 (18)	16 (23)	16 (27)	21 (33)	10 (17)	10 (16)
Emotional functioning	14 (23)	15 (21)	10 (16)	13 (19)	9 (15)	10 (16)	8 (14)	10 (16)
Cognitive functioning	**20** (32)	**9** (13)	13 (22)	11 (16)	13 (22)	12 (19)	10 (17)	12 (19)
Social functioning	26 (43)	19 (27)	8 (13)	13 (19)	12 (20)	12 (19)	11)20)	11 (17)
Global health status/QOL	**32** (52)	**20** (29)	6 (10)	10 (14)	15 (25)	12 (19)	6 (10)	14 (23)
EORTC QLQ-C30 [b]								
Symptom Scales								
Fatigue	42 (68)	34 (49)	**6** (10)	**22** (31)	22 (37)	23 (36)	9 (16)	9 (14)
Nausea/vomiting	15 (24)	9 (13)	1 (2)	4 (6)	4 (7)	5 (8)	2 (3)	6 (9)
Pain	**38** (61)	**25** (36)	7 (11)	15 (21)	15 (25)	17 (26)	**7** (12)	**17** (27)
Dyspnea	**19** (31)	**6** (9)	6 (10)	13 (19)	5 (8)	9 (14)	5 (9)	8 (13)
Insomnia	21 (33)	20 (29)	8 (13)	13 (19)	11 (19)	12 (19)	10 (17)	12 (19)
Appetite loss	**23** (51)	**13** (19)	5 (8)	9 (13)	11 (19)	6 (9)	3 (6)	7 (11)
Constipation	19 (31)	11 (16)	5 (8)	6 (9)	9 (15)	4 (6)	3 (5)	5 (8)
Diarrhea	6 (10)	8 (12)	4 (7)	5 (7)	5 (8)	4 (6)	3 (5)	8 (13)
Financial difficulties	5 (8)	6 (9)	6 (10)	4 (7)	3 (5)	6 (9)	4 (7)	5 (8)
EORTC QLQ-H&N35 [b]								
Symptom scales								
Pain	**38** (61)	**26** (38)	1 (2)	7 (10)	9 (15)	9 (14)	7 (12)	7 (11)
Swallowing	**35** (56)	**25** (36)	7 (11)	9 (13)	13 (22)	10 (16)	5 (9)	11 (17)
Senses	**33** (53)	**19** (27)	7 (11)	11 (16)	14 (24)	14 (22)	9 (16)	11 (17)
Speech	**42** (67)	**31** (44)	4 (6)	8 (11)	11 (19)	8 (12)	11 (19)	14 (22)
Social eating	**34** (54)	**19** (27)	3 (5)	3 (4)	**16** (27)	**5** (8)	6 (10)	9 (14)
Social contact	15 (24)	11 (16)	3 (5)	6 (9)	8 (13)	4 (6)	2 (3)	4 (6)
Less sexuality	**21** (34)	**10** (14)	7 (12)	10 (15)	11 (21)	10 (19)	8 (16)	5 (9)
Teeth problems	11 (18)	15 (22)	12 (20)	9 (14)	10 (17)	11 (18)	7 (12)	2 (3)
Opening mouth	**31** (50)	**20** (30)	6 (10)	6 (9)	12 (20)	11 (17)	5 (9)	6 (9)
Dry mouth	22 (35)	20 (29)	12 (19)	6 (9)	12 (20)	15 (23)	10 (17)	7 (11)
Sticky saliva	27 (44)	23 (33)	7 (11)	9 (13)	11 (19)	9 (14)	6 (11)	9 (14)
Coughing	**26** (42)	**16** (24)	8 (13)	13 (20)	4 (7)	11 (17)	11 (19)	8 (13)
Feeling ill	**29** (47)	**18** (27)	4 (7)	6 (9)	3 (5)	8 (12)	5 (9)	5 (8)
Use of pain killers	26 (41)	20 (29)	4 (6)	7 (10)	7 (12)	7 (11)	3 (5)	8 (12)
Use of nutritional supplements	**19** (30)	**8** (11)	4 (6)	2 (3)	10 (17)	4 (6)	4 (7)	2 (3)
Use of feeding tube	9 (14)	4 (6)	2 (3)	0	1 (1)	0	1 (2)	1 (2)
Weight loss	**26** (41)	**12** (17)	2 (3)	6 (9)	7 (12)	4 (6)	7 (12)	3 (5)
Weight gain	5 (8)	8 (12)	11 (19)	12 (18)	7 (12)	6 (9)	9 (16)	5 (8)

i-group intervention group, *c-group* comparison group

Bold figures indicate a difference of ≥10 patients between groups

[a] PAIS-SR: figures based on a change of at least one standard deviation

[b] EORTC QLQ-C30 & H&N35: Improvement by at least 10 points (better QOL and functioning or fewer symptoms)

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